PATENT
Docket No.: 33677-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Gary E. Borodic, M.D.		
Serial No.	:	09/382,837	**Group Art Unit** :	1644
Filed	:	August 25, 1999	**Examiner**	:G.R. Ewoldt, Ph.D.
For	:	***Chemodenervating Pharmaceutical As Anti-Inflammatory Agent***		

RESPONSE TO RESTRICTION REQUIREMENT

BY FACSIMILE
(703) 308-4315
ATTN: G.R. Ewoldt, Ph.D.

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Sir:

In response to Examiner's Restriction Requirement mailed January 26, 2001, Applicant provisionally elects to pursue prosecution of Invention I. This election is made with traverse. Applicant respectfully submits that, properly understood, groups I, II, III, IV and VI of the restricted claims are properly presented in the same application because the claims are technically related and so undue diverse searching should not be required. Thus, the claims in these groups should be examined together. M.P.E.P. §803.

In particular, the specification of the application makes it clear that allergic blepharoconjunctivitis, type I hypersensitivity, hay fever, and rhinitis, are all disorders for which treatment with a chemodenervating agent induces a reduction in inflammation. For example, on page twenty of the specification (with numbering starting on the page headed "FIELD OF INVENTION"), Applicant discloses under "General Test Results", that in patients treated with a chemodenervating pharmaceutical who exhibit "exertion urticaria, spasmodic torticollis, type I hypersensitivity, pollen induced conjunctivitis, and allergic blepharoconjunctivitis", Applicant has observed "improvement in erythema", "improvement in sensation, pain and/or itching", "improvement in edema", "differential in apparent heat release", and "relaxation of human

muscle spasms". These are the same clinical properties that Applicant disclosed as "characterizing inflammation" in the "Experimental Model" section on the same page. Thus, the method of treatment with a chemodenervating pharmaceutical of each of the particular disorders listed above—exertion urticaria, spasmodic torticollis, type I hypersensitivity, pollen-induced conjunctivitis, and blepharoconjunctivitis—as well as other inflammatory conditions such as blepharospasm, internal inflammatory disease, rheumatoid arthritis, and other disorders (Inventions III, IV, and VI), is closely related to the disclosed generic method of treatment of inflammation with chemodenervating pharmaceuticals (Invention I).

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It is also clear from the "Summary of the Invention", in particular pages five and six of the specification, that Applicant considers effects on mast cell degranulation to be a key mechanism whereby chemodenervating pharmaceuticals exert their anti-inflammatory effects when used to treat disorders that include inflammation as an element of their clinical presentation. For example, Applicant discloses that "[a] number of these mast cell constituents play a role in the inflammatory response". Thus, it is clear that Applicant also considers methods of blocking mast cell degranulation or treating inflammatory diseases in which mast cells play a role with chemodenervating pharmaceuticals (Invention II) to be technically related to the claimed method of treatment of inflammation with chemodenervating pharmaceuticals (Invention I).

Based upon this analysis, Applicant respectfully submits that the Examiner would not be subject to undue non-overlapping prior art searching in the examination of the claims of what the Examiner has referred to as Inventions I, II, III, IV, and VI. As the Examiner has noted, all of the claims in these groups are classified in the same Class, 424, and Subclass, 282.1. For the reasons stated above, the methods of treating the different diseases would not appear to require separate and distinct searches. For all of the foregoing reasons, it is respectfully

submitted that the restriction requirement should be withdrawn and an action on the merits of all the claims is respectfully solicited.

An extension of time for one month is believed necessary for this response, and is hereby petitioned for. However, any further extension of time which may be required for this response is also hereby petitioned for. The Commissioner is authorized to charge the $110 fee believed necessary, and any additional fee which may be required for this paper, to Deposit Account Number 13-3250, Order No. 33677-00000.

An early and favorable examination on the merits is respectfully requested.

Respectfully submitted,
Milbank, Tweed, Hadley & McCloy LLP

March 26, 2001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Gary E. Borodic, M.D.	
Serial No.	:	09/382,837	**Group Art Unit**: 1644
Filed	:	August 25, 1999	**Examiner**: G.R. Ewoldt, Ph.D.
For	:	***Chemodenervating Pharmaceutical As Anti-Inflammatory Agent***	

PRELIMINARY AMENDMENT AND REQUEST BY APPLICANT PURSUANT TO 37 C.F.R. § 1.607 FOR INTEREFERENCE WITH U.S. PATENT NO. 6,063,768 TO FIRST

Asst. Commissioner for Patents
Washington, D.C. 20231

Sir:

IN THE SPECIFICATION

Please add the following two sentences at the beginning of the specification, just before the heading "Field of Invention": "This application claims the benefit of U.S. Provisional Application Ser. No. 60/097,846, filed Aug. 25, 1998. U.S. Provisional Application Ser. No. 60/097,846, filed Aug. 25, 1998, is hereby incorporated herein in its entirety."

A1

IN THE CLAIMS

Please add the following new claims:

A2

17. A method for treating neurogenic inflammation comprising, administering a therapeutically effective amount of *Clostridium botulinum* toxin to antagonize the action of at least one neurogenic inflammatory mediator, whereby said toxin interrupts a neurogenic pathway associated with said neurogenic inflammation.

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18. The method of claim 17, wherein the botulinum toxin is selected from the group